

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY,

Plaintiff,

v.

ACTAVIS ELIZABETH LLC,
GLENMARK PHARMACEUTICALS
INC., USA, SUN PHARMACEUTICAL
INDUSTRIES LIMITED, SANDOZ
INC., MYLAN PHARMACEUTICALS
INC., APOTEX INC., AUROBINDO
PHARMA LTD., TEVA
PHARMACEUTICALS USA, INC.,
SYNTHON LABORATORIES, INC.,
ZYDUS PHARMACEUTICALS USA,
INC.,

Defendants.

Civil Action No. 07-3770 (DMC)(MF)

RETURN DATE: OCTOBER 4, 2010

Redacted - Public Version

DEFENDANT MYLAN PHARMACEUTICALS
INC.'S BRIEF IN SUPPORT OF MOTION TO
RECONSIDER ORDER REQUIRING PLAINTIFF ELI LILLY &
COMPANY TO POST SECURITY IN THE AMOUNT OF \$10 MILLION

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TABLE OF CONTENTS

	<u>Page</u>
TABLE OF AUTHORITIES	ii
I. BACKGROUND	2
II. ARGUMENT	3
III. CONCLUSION.....	6

TABLE OF AUTHORITIES

Cases

Page(s)

Ace American Ins. Co. v. Wachovia Ins. Agency Inc.,
Civ. Action No. 08-4369 (JLL), 2008 WL 4951239 (D.N.J. Nov. 18, 2008)4

Don Post Studios, Inc. v. Cinema Secrets, Inc.,
148 F. Supp. 2d 572 (E.D. Pa. 2001)5, 6

Mead Johnson & Co. v. Abbott Labs.,
201 F.3d 883 (7th Cir. 2000)5

Sprint Commc's Co. L.P., v. Cat Communications Int'l Inc.,
335 F.3d 235 (3d Cir. 2003).....5

Virginia Plastics Co. v. Biostim, Inc.,
820 F.2d 76 (3d Cir. 1987).....5

Statutes and Rules

35 U.S.C. § 112.....1

Fed, R. App. P. 4(a)(4).....4

Fed, R. App. P. 4(a)(4)(B)(I)4

Fed. R. Civ. P. 59(e)3, 4

I. Civ. R. 7.1(i).....3, 4

Defendant Mylan Pharmaceuticals Inc. ("Mylan") submits this Brief in support of its Motion to Reconsider the Court's August 18, 2010 Order to the extent it required Plaintiff Eli Lilly & Company ("Lilly") to post security in the amount of \$10 million dollars.¹ This Court required Lilly to post a \$10 million dollar bond in connection with the grant of a fourteen (14) day injunction to apply to all Defendants. Unfortunately, a bond of \$10 million dollars will not even adequately compensate Mylan should it later be determined that Mylan was wrongfully enjoined. This is because, here, the actual losses to Mylan within the first fourteen days of generic entry are [REDACTED]. And since Mylan had no way of knowing that the Court would issue an injunction for fourteen days, Mylan did not have an opportunity to adequately quantify what its losses would be during such an injunction period.

Moreover, on August 26, 2010, the Federal Circuit issued an Order continuing this Court's injunction, pending the Federal Circuit's receipt and consideration of Lilly's Motion for an Injunction. *See* Declaration of Victoria E. Spataro ("Spataro Dec."), Ex. 1. Therefore, at present, Mylan has no way of knowing whether the current injunction will only be in place for two weeks or longer. Thus, a bond of only \$10 million dollars can not properly compensate Mylan for the losses it will suffer during the injunction period – a length of time which, at present, neither the Parties nor this Court can adequately predict. And, while the duration of the injunction is somewhat unclear, Mylan only asks that Lilly, at a minimum, post a bond which more adequately reflects the actual losses suffered by Mylan during this Court's contemplated fourteen day injunction period – namely, security in the amount of [REDACTED].

¹ In light of the recent flurry of applications and filings in this matter, both before this Court and the U.S. Court of Appeals for the Federal Circuit, we are filing the within motion at this time and would appreciate the Court's indulgence in considering this application at the Court's earliest convenience.

I. BACKGROUND

In the wake of the Court's August 12, 2010 Order, finding the U.S. Patent No. 5,658,590 ("the '590 patent") invalid, Mylan moved the Court for immediate entry of final judgment. (D.E. 658.) On August 16, 2010, Lilly moved the Court, *inter alia*, to enjoin Mylan and the other Defendants from launching any generic versions of Lilly's Strattera® product. On August 18, 2010 Mylan filed its opposition to Lilly's Motion, including the August 17, 2010 Declaration of Tony Mauro (the "Original Mauro Declaration"). See D.E. 667-1 (attached as Exhibit 2 to the Spataro Dec.) As explained in the Original Mauro Declaration, [REDACTED]

As the Court will recall, Mr. Mauro also explained [REDACTED]

But Mr. Mauro's estimate does not evenly break down to a simple \$5 million dollars a week of gross margin revenue². And because Lilly's Motion did not explicitly seek a two-week

² The Court did not explain its rationale for setting the Security at \$10 million. While Mylan is unaware of the calculation method utilized by the Court, it can be posited that the \$10 million figure can be derived from the \$120 million in gross margin revenue associated with the 180-day period of exclusivity, as set forth in the Original Mauro Declaration. In other words, if one divides \$120 million by 180 days, the resulting ratio is \$5 million/week. The 14-day temporary injunction, therefore, would correspond to \$10 million.

injunction, Mr. Mauro did not estimate the value of the sales associated within the first fourteen days of exclusivity.

As Mr. Mauro now explains in the accompanying Second Mauro Declaration, the damages that Mylan will suffer during the first fourteen days of exclusivity far exceed \$10 million dollars. *See* Second Mauro Declaration at ¶¶ 4-6. This is because, absent the injunction,

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] within fourteen days from the date of the Court's decision or through the expiration of the Court's fourteen day injunction. *Id.* at ¶ 6. But Mylan never had an opportunity to present such facts to this Court. And the temporary injunction awarded to Lilly means that Mylan will not receive that revenue over the next two weeks. As such, Mylan respectfully requests that this Court increase Lilly's bond to, at the very least, compensate Mylan for the actual revenue lost during the two week injunction period, which now prevents Mylan from launching its product before other generic companies were commercially prepared to do so.

II. ARGUMENT

Federal Rule of Civil Procedure 59(e) permits a party to move to alter or amend a judgment within 28 days of entry of the judgment. *See* Fed. R. Civ. P. 59(e).³ Local Civil Rule

³ On August 25, 2010, Lilly filed a Notice of Appeal to the Federal Circuit as to the Court's Orders in this case. (D.E. 687). The District Court is not divested of its jurisdiction to entertain Mylan's Rule 59(e) motion by Lilly's Notice of Appeal. The issue of the bond amount is not

7.1(i) provides that a motion for reconsideration “setting forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked” may be filed within fourteen days after entry of an order. L. Civ. R. 7.1(i). As has been recognized in this Court, “[t]here are three grounds for granting a motion for reconsideration (1) an intervening change in controlling law has occurred; (2) evidence not previously available has become available; or (3) it is necessary to correct a clear error of law or prevent manifest injustice.” *Ace American Ins. Co. v. Wachovia Ins. Agency Inc.*, Civ. Action No. 08-4369 (JLL), 2008 WL 4951239 (D.N.J. Nov. 18, 2008) (granting motion for reconsideration and vacating stay pending appeal where original stay was granted on the basis of an incomplete factual record). Reconsideration of the August 18 Order’s Security amount is warranted under both the second and third prongs.

The Second Mauro Declaration makes clear that the harm that Mylan will suffer as a result of the August 18 Order’s two-week temporary injunction will cause damage that exceeds the \$10 million in Security that Lilly has been ordered to post to account for lost revenue to all Defendants in the case. Prior to the August 18 Order, Mylan had not determined the damages that would be associated with a two-week injunction, because Lilly had not sought a temporary injunction of that specific duration. Had Mylan known that the Court intended to enjoin defendants to a specific, limited period of time (fourteen days from entry of judgment), Mylan would have quantified its losses for that particular period prior to the Court ordering Lilly to post security in the amount of \$10 million. Therefore, Mylan respectfully submits that the newly adduced information contained in the Second Mauro Declaration warrants reconsideration and amendment of the August 18 Order to increase the Security amount to [REDACTED]

being appealed by Lilly, but even if the issue of the bond amount was currently on appeal, the District Court would nonetheless retain jurisdiction to entertain Mylan’s Rule 59(e) motion under Federal Rule of Appellate Procedure 4(a)(4)(B)(I).

Specifically, Mr. Mauro explains that, [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] Nevertheless, due to the injunction, Mylan is unable to launch. And without adequate security Mylan is not afforded any protection should the Federal Circuit conclude that Mylan was wrongfully enjoined. Thus, the current bond of \$10 million dollars [REDACTED] Mylan will suffer during the two week injunction period.

The security requirement is designed to protect the enjoined party by providing a fund “for the payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined.” *Sprint Commc’s Co. L.P., v. Cat Communications Int’l Inc.*, 335 F.3d 235, 240-41 (3d Cir. 2003). To further this purpose, “[w]hen setting the amount of security, district courts should err on the high side.” *Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883, 888 (7th Cir. 2000) (observing that it is reversible error for a district court to set security at too low an amount).

Mylan will thus be entitled to recover on the Security if it can prove that it has been wrongfully enjoined and that it has suffered damages. See *Sprint Commc’s*, 335 F.3d at 241; *Virginia Plastics Co. v. Biostim, Inc.*, 820 F.2d 76, 80-81 & n. 6 (3d Cir. 1987). And Mylan’s losses become even larger should the injunction period be longer than fourteen days in light of the Federal Circuit’s August 26 Order, continuing the injunction pending receipt and

consideration of Lilly's Motion for an Injunction in the Federal Circuit. For these additional reasons, Lilly should be required to post a substantially higher bond⁴.

Lilly can be expected, however, to argue that Mylan's recovery should be limited to the Security, even if it demonstrates that the damages resulting from the temporary injunction exceed that amount. *See Don Post Studios, Inc. v. Cinema Secrets, Inc.*, 148 F. Supp. 2d 572, 575 (E.D. Pa. 2001) ("As a general rule, the damages of a party that has been wrongfully enjoined are capped at the amount of the bond.")⁵ But the very purpose of the security requirement, the protection of the enjoined party, would be frustrated were Lilly, the party enjoying the benefit of the injunction, able to use the August 18 Order's Security to cap the amount of damages for which it can be liable to Mylan. To ensure that Mylan is adequately compensated in the event that they are able to show that Lilly was not entitled to the temporary injunction, Lilly should be ordered to post security in an amount [REDACTED] – an amount which merely compensates Mylan for its actual losses during the two week period.

III. CONCLUSION

[REDACTED]
[REDACTED] Eighteen days have since past and Mylan is currently enjoined from launching. If it is later determined that the injunction preventing Mylan's launch was improvidently granted, Mylan should be afforded the protection of an adequate security bond. For all the foregoing reasons, Mylan respectfully requests that the Court grant its Motion to reconsider and amend the August 18 Order to increase the Security to [REDACTED]

⁴ Mylan reserves the right to move the Court to set a higher amount of security in the event the Court's injunction exceeds the initial two week period.

⁵ If an application for damages becomes necessary, Mylan reserves its right to argue that it is entitled to damages in excess of the Security amount under the standards articulated in *Don Post Studios*.

Respectfully submitted,

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